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Evaluation Report ERC2011-05

Veridian 0.33G and Veridian 25WG containing Thiamethoxam

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Overview

Registration Decision for Thiamethoxam

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Thiamethoxam Technical, Veridian 0.33G and Veridian 25WG, containing the technical grade active ingredient thiamethoxam, to control European chafer, Japanese beetle, black turfgrass ataenius and masked chafer on turf.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk reduction measures are followed, the applicant must submit additional scientific information as a condition of registration.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Thiamethoxam Technical, Veridian 0.33G and Veridian 25WG.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For

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1 Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Thiamethoxam?

Thiamethoxam is a systemic insecticide belonging to the neonicotinoid class of compounds. Thiamethoxam moves through the translocation system of the plant, and affects insects by both contact and ingestion exposure. It interferes with the insect's central nervous system causing tremors, loss of coordination, irreversible cessation of feeding and eventual death. It is effective against all insect life stages except eggs. Veridian 0.33G and Veridian 25WG are applied as foliar broadcast sprays to turf, for control of larvae of European chafer, Japanese beetle, black turfgrass ataenius and masked chafer.

Health Considerations

Can Approved Uses of Thiamethoxam Affect Human Health?

Thiamethoxam is unlikely to affect your health when used according to label directions.

When assessing health risks, two key factors are considered: the levels at which no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only those uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Thiamethoxam was of moderate toxicity following oral ingestion. Thiamethoxam was not found to be genotoxic. Thiamethoxam did not cause cancer in rats, but did produce tumours in mice. However, the process of tumour formation in the mouse is not expected to occur in humans under typical exposure conditions. Other health effects in animals included effects in the liver, kidneys and nervous system. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in test animals.

When thiamethoxam was given to pregnant animals, effects on the offspring were observed at doses that did not have health effects in the mother, indicating that the young were more sensitive to thiamethoxam than the adult animal. Consequently, extra protective measures were applied in the risk assessment to further reduce the allowable level of human exposure to thiamethoxam.

Veridian 0.33G is considered to be of low toxicity to rats via the oral and inhalation routes, and is of low toxicity to rabbits via the dermal route. It is minimally irritating to the eyes and non-irritating to the skin of rabbits. It is considered to be a dermal sensitizer in guinea pigs.

Veridian 25WG is considered to be of low toxicity to rats via the oral and inhalation routes, and is of low toxicity to rabbits via the dermal route. It is mildly irritating to the eyes and slightly irritating to the skin of rabbits. It is not considered to be a dermal sensitizer to guinea pigs.

Risks in Residential and Other Non-Occupational Environments

Bystander risks are not of concern if label directions and precautionary measures are followed.

Adults, youth and children may come in contact with thiamethoxam residues on skin or through non-dietary (incidental) oral ingestion by entering freshly treated commercial, recreational or residential lawns (up to one month). Potential exposure and risks to these individuals are not of concern if label directions and precautionary measures are followed.

Occupational Risks From Handling Veridian 0.33G and Veridian 25WG

Occupational risks are not of concern when the products are used according to the label directions, which include precautionary measures.

Commercial applicators and lawn care operators who mix, load and/or apply Veridian 25WG or Veridian 0.33G, as well as workers re-entering freshly treated lawns may come in direct contact with thiamethoxam residues on the skin and by inhalation, intermittently for up to six months. Because there is a concern with users coming into direct contact with thiamethoxam residues on the skin or through inhalation, risk reduction measures such as specifying personal protective equipment and interval for re-entering treated areas are required on the Veridian 25WG and Veridian 0.33G labels. Taking into consideration these precautionary measures, a single application per year and the expected exposure period for workers, the risks to these individuals are not a concern.

Environmental Considerations

What Happens When Thiamethoxam Is Introduced Into the Environment?

Environmental risk from thiamethoxam can be minimized when used according to label directions.

Thiamethoxam enters the environment when used on turf for control of insect pests as either a granule or foliar spray. Thiamethoxam is persistent in the environment with the main route of transformation in the terrestrial environment being in soil. Thiamethoxam is not expected to volatilize, however, it is expected to leach.

The only major transformation product identified in the terrestrial field dissipation studies was clothianidin. Clothianidin is a registered insecticide in its own right. Clothianidin is persistent in the environment with the main route of transformation in the terrestrial environment being in soil. Clothianidin is not expected to volatilize; however, it is expected to leach.

Although the use pattern of this product does not include direct application to water, the possibility that aquatic systems will be exposed to thiamethoxam and its major transformation products, directly or indirectly, cannot be ruled out. Thiamethoxam can enter the aquatic environment through spray drift and runoff from treated turf. In aquatic systems, thiamethoxam transforms quickly via aerobic biotransformation to two transformation products. Further discussion regarding these transformation products occurs in the Science Evaluation of this document. The transformation product clothianidin is slightly persistent in the aquatic environment.

The risk to the environment was assessed for thiamethoxam and the thiamethoxam end-use products Veridian 0.33G and Veridian 25WG. The screening level risk assessment identified the potential risks to bees, terrestrial plants and aquatic invertebrates. Exposure to bees from turf application is expected to be lower than currently registered products containing thiamethoxam. Additional characterization of exposure to bees from drift to adjacent habitats resulted in negligible risk from contact exposure and less risk from oral ingestion. To help mitigate for potential toxicity, precautionary label statements are required. Further characterization of the risk to terrestrial plants and aquatic invertebrates from off field spray deposition indicated that no-spray buffer zones of one metre are required to protect sensitive habitats downwind of the site of application.

Value Considerations

What Is the Value of Veridian 0.33G and Veridian 25WG?

Veridian 0.33G and Veridian 25WG control larvae of four insect species that infest turf in Canada.

A single application of Veridian 0.33G and Veridian 25WG can control larvae of European chafer, Japanese beetle, black turfgrass ataenius and masked chafer on turf. Use of this insecticide is compatible with current management practices, especially if users monitor pest populations and make applications during the period of peak egg-laying.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Veridian 0.33G and Veridian 25WG to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Mixers and loaders must wear a long-sleeved shirt, long pants, chemical resistant gloves, socks and boots. Applicators must wear a long-sleeved shirt, long pants, socks and boots. Workers must not enter treated areas within the first 12 hours after application.

Mixers, loaders, and applicators of Veridian 0.33G must also wear a suitable dust mask approved by NIOSH/MSHA. Veridian 0.33G must not be applied by hand.

Environment

Hazard statements are required for aquatic organisms and bees. Appropriate precautionary measures are also required to address risk to bees.

A no-spray buffer zone of one metre is required for aquatic habitats to mitigate risk of spray drift of Veridian 25WG to aquatic organisms. A no-spray buffer zone of 1 metre is also required to mitigate the potential risk of spray drift of Veridian 25WG to terrestrial plants.

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of this Evaluation Report or in the section 12 Notice associated with these conditional registrations. The applicant must submit the following information by September 1, 2013.

Environment

- A field dissipation study with thiamethoxam applied to turf.
- A new hive study with thiamethoxam.

Other Information

As these conditional registrations relate to a decision on which the public must be consulted,[3] the PMRA will publish a consultation document when there is a proposed decision on applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

[3] As per subsection 28(1) of the *Pest Control Products Act*.

The test data cited in this Evaluation Report (i.e. the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

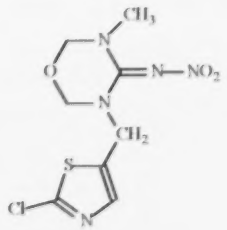
Science Evaluation

Thiamethoxam

Regulatory Note REG2001-03, *Thiamethoxam, Helix, Helix XTra* and Evaluation Report ERC2007-01, *Thiamethoxam* provide summaries of data previously reviewed and rationales for the respective conditional registration decisions for seed treatment uses on canola and mustard and spray application to pome fruit and potatoes. The information captured herein relates to new information provided to the Agency in support of a registration for turf uses.

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Thiamethoxam
Function	Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	(3-(2-Chloro-1,3-thiazol-5-ylmethyl)-5-methyl-1,3,5-oxadiazinan-4-ylidene(nitro)amine
2. Chemical Abstracts Service (CAS)	3-[(2-Chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-*N*-nitro-4*H*-1,3,5-oxadiazin-4-imine
CAS number	153719-23-4
Molecular formula	$C_8H_{10}ClN_5O_3S$
Molecular weight	291.7
Structural formula	
Purity of the active ingredient	98% nominal

1.2 Physical and Chemical Properties of the Active Ingredient and End-use Products

Technical Product—Thiamethoxam Technical

Property	Result
Colour and physical state	Off-white fine powder
Odour	Odourless
Melting range	139.1°C
Boiling point or range	Not applicable. The product is a solid
Density	1.57×10^{3} kg/m^{3}
Vapour pressure at 20°C	2.7×10^{-9} Pa
Henry's law constant at 20°C	1.9×10^{-10} Pa·m^{3}/mol
Ultraviolet (UV)-visible spectrum	No significant absorption at wavelength over 300 nm in neutral, acidic and basic solutions
Solubility in water at 25°C	4.1 g/L
Solubility in organic solvents at 20°C (g/100 mL)	Solvent — Solubility dichloromethane — 11 acetone — 4.8 methanol — 1.3 ethyl acetate — 0.7 toluene — 0.068 octanol — 0.062 hexane — < 0.0001
n-Octanol–water partition coefficient (K_{ow})	log K_{ow} = -0.13 ± 0.0017 at 25°C
Dissociation constant (pK_a)	No dissociation within the pH range 2 to 12
Stability (temperature, metal)	No thermal effect (peak) found between room temperature and the melting point of the substance. The product is not changed by contact with metals (stainless steel, cast steel, tin & aluminum) and with metal ions (Zn^{+2}, Al^{+3}, Cu^{+2} and Fe^{+2}).

End-use Product—Veridian 0.33G

Property	Result
Colour	Light tan
Odour	Slightly pungent
Physical state	Solid
Formulation type	Granular
Guarantee	0.33% Thiamethoxam
Container material and description	100 g to 40 kg; foil or polyethylene bags
Density	0.57–0.82 g/cm^3
pH of 1% dispersion in water	6–9
Oxidizing or reducing action	Not expected to be an oxidizing substance
Storage stability	The product has been shown to be stable over one year at ambient temperature in foil and polyethylene packaging.
Corrosion characteristics	There was no observable corrosion and none is expected under ambient storage conditions in commercial packaging.
Explodability	Product not expected to be explosive

End-use Product—Veridian 25WG

Property	Result
Colour	Light Brown
Odour	Musty
Physical state	Solid
Formulation type	Wettable granules
Guarantee	25% Thiamethoxam
Container material and description	100 g to 3 kg, plastic Jug
Density	0.47 g/cm^3 at 20°C
pH of 1% dispersion in water	7–11 (1% solution at 25°C)
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	The product is shown to be stable after storage for at least three years at ambient temperature in non-fluorinated high density polyethylene packaging.
Corrosion characteristics	No physical changes are observed in the test container (HDPE) after storage for at least three months.
Explodability	Test results show the product not to be explosive.

1.3 Directions for Use

Veridian 0.33G and Veridian 25WG are for use on turgrasses on golf courses, residential lawns, commercial grounds (office/shopping complexes, airports), parks, playgrounds, athletic fields and sod farms to control larvae of four pest species—European chafer, Japanese beetle, black turfgrass ataenius and masked chafer. Veridian 0.33G is applied as a granular broadcast application while Veridian 25WG is applied as a foliar broadcast application; both products are applied once per season at 225 to 300 g a.i./ha. It is recommended that the application be made between peak adult flight and peak egg hatch. The higher application rate is recommended for control of larger larvae.

1.4 Mode of Action

Thiamethoxam is a second generation neonicotinoid and an agonist of the insect nicotinic acetylcholine receptor. It affects synapses in the insect central nervous system, and has contact, stomach and systemic activity, causing tremors, loss of coordination, irreversible cessation of feeding and eventual death. When applied as a foliar spray, it has translaminar activity.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Thiamethoxam Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

High-performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices and environmental media. Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Refer to Regulatory Note REG2001-03, *Thiamethoxam, Helix, Helix XTra* and Evaluation Report ERC2007-01, *Thiamethoxam* for toxicology summaries of thiamethoxam.

Veridian 0.33G is considered to be of low toxicity to rats via the oral (LD_{50} >5050 mg/kg) and inhalation routes (LC_{50} >3.32 mg/L), and is of low toxicity to rabbits via the dermal route (LD_{50} >5050 mg/kg). It is minimally irritating to the eyes and non-irritating to the skin of rabbits. It is considered to be a dermal sensitizer in guinea pigs.

Veridian 25WG is considered to be of low toxicity to rats via the oral (LD_{50} >5000 mg/kg) and inhalation routes (LC_{50} >2.79 mg/L), and is of low toxicity to rabbits via the dermal (LD_{50} >2000 mg/kg). It is mildly irritating to the eyes and slightly irritating to the skin of rabbits. It is not considered to be a dermal sensitizer to guinea pigs.

3.2 Determination of Acute Reference Dose

The recommended acute reference dose for thiamethoxam is 0.12 mg a.i./kg bw. Refer to Evaluation Report ERC2007-01, *Thiamethoxam* for details.

3.3 Determination of Acceptable Daily Intake

The recommended acceptable daily intake for thiamethoxam is 0.004 mg a.i./kg bw/day. Refer to Evaluation Report ERC2007-01, *Thiamethoxam* for details.

3.4 Occupational, Residential and Bystander Risk Assessment

3.4.1 Toxicological Endpoints

Commercial applicators and lawn care operators have potential for an intermittent exposure to thiamethoxam over a short- to intermediate-term duration (June to September) predominantly by the dermal route. In addition, there is potential for a short-term dermal exposure to adults, youth and children who may enter treated commercial, residential or recreational lawns including golf courses to conduct various activities (for example, to play golf).

The no observed adverse effect level (NOAEL) of 1.2 mg/kg bw/day, selected for a short- to intermediate-term occupational and bystander exposure and risk assessment from the Evaluation Report ERC2007-01, *Thiamethoxam* is considered appropriate for the short- to intermediate-term turf exposure and risk assessment.

3.4.1.1 Dermal Absorption

Based on in vivo rodent dermal absorption studies conducted with various formulations of thiamethoxam, as summarized in Evaluation Report ERC2007-01, *Thiamethoxam*, the dermal absorption value for thiamethoxam was determined to be 2.5%.

3.5 Occupational Exposure and Risk

3.5.1 Mixer/Loader/Applicator Exposure and Risk Assessment

Based on a single application of Veridian 25WG or Veridian 0.33G, from June to September, commercial applicators and lawn care operators have potential for an intermittent exposure to thiamethoxam over a short-to intermediate-term duration. Commercial applicators and lawn care operators will mix/load dry formulations and apply outdoors on commercial (golf courses, sod farms, office and shopping complexes, airports) and/or residential and recreational lawns Veridian 25WG is applied by a ground boom or by a handheld turf gun sprayer for broadcast applications, or by a backpack sprayer for spot treatments. Veridian 0.33G is applied by a granular tractor drawn spreader or by a push-type rotary spreader. The label specifies not to apply Veridian 0.33G by hand. Depending on the turf site and equipment used, the typical turf area that can be treated in one day ranges from 0.4 to 30 ha.

No chemical-specific mixer/loader/applicator exposure data on turf are available. Therefore, the dermal and inhalation unit exposure data from the Pesticide Handlers Exposure Database (PHED) Version 1.1, which is a compilation of generic mixer/loader/applicator passive dosimetry data, or from the Outdoor Residential Exposure Task Force (ORETF) passive dosimetry studies on turf, were used to generate scenario-specific exposure estimates for workers. All unit exposure estimates from these data sources are normalized for kg of active ingredient handled. Depending on the formulation type, and turf application site, PHED or ORETF data were subset to represent several exposure scenarios for mixers/loaders/applicators: 1) dry flowable open mix, load and open cab ground boom application; 2) open pour dry mix, load and backpack application; 3) low pressure turf gun application; 4) open granular mix, load and solid broadcast granular tractor drawn open cab application; and 5) push-type spreader. The exposure estimates are based on a mixer/loader/applicator wearing a single layer of clothing (long pants and a long sleeved shirt) and gloves.

Dermal exposure was estimated by coupling the unit exposure values with the amount of product handled per day and the dermal absorption value. Inhalation exposure was estimated by coupling the unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight.

Exposure estimates were compared to the toxicological end points to obtain the margin of exposure (MOE); the target MOE is 300. As the exposures via the dermal and inhalation routes contributed to the same toxic effect, i.e. one NOAEL was selected for all routes of exposure; the route-specific MOEs were combined. MOEs for a commercial applicator or a lawn care operator mixing, loading and applying thiamethoxam to turf for all scenarios were above the target MOE of 300 (Appendix I, Table 2).

3.5.2 Postapplication Exposure and Risk

Golf course and sod farm workers who enter Veridian 25WG and Veridian 0.33G treated sites to conduct turf maintenance activities have potential for intermittent short-term (<1 week) dermal exposure to thiamethoxam. Inhalation exposure was not considered to be a significant route of exposure for individuals re-entering treated turf as thiamethoxam is non-volatile based on its very low vapour pressure and due to the dilution of formulation in much greater volume of outdoor air.

3.5.2.1 Turf Transferable Residue (TTR) Study

Transferable residues from turf were determined for two formulations of thiamethoxam at three test sites in the United States: California, Pennsylvania and North Carolina. At each test site, the US formulations, Meridian™ 25WG (wettable granules) by a turf gun and Meridian 0.33G (granular) by a drop spreader were applied at the label rates in the intended use period (May–August). After application, two of four established treated plots (two for each formulation) were sprinkler irrigated (watering-in). Transferable residues from turf were sampled using Modified California Roller Technique. From each treated plot at each test site, four samples per sampling interval, before application, immediately following the application (non-irrigated plots), 4 hrs, 8 hrs, 24 hrs, 2, 4, 7, 10, 14 and 21 days following application, were collected. No control plot was used in the study.

Only TTR after application of the WG formulation from the non-irrigated plots at each test site were above the limit of quantification (>LOQ) at each sampling time and were used in the dissipation regression analysis. Immediately following the application of the WG formulation, thiamethoxam residues reached a peak of 0.0124 µg/cm^2 (0.41% of applied) at the California site, 0.0105 µg/cm^2 (0.35% of applied) at the Pennsylvania site and 0.0075 µg/cm^2 (0.25% of applied) at the North Carolina site. Residue regression analysis resulted in the half lives ($t_{½}$) of 1.17 hours (California), 0.36 hours (Pennsylvania) and 1.34 hours (North Carolina). There was a rainfall between 8 and 24 hr of sampling at the Pennsylvania site. TTR reached (<LOQ) in 2 days at the Pennsylvania site and by 7 days of application at the California and North Carolina sites. The r^2 values were 0.99 for the California site, 0.97 for the Pennsylvania site and 0.70 for the North Carolina site.

Overall, the study was found to be acceptable for estimating exposure to thiamethoxam on turf as only minor limitations were noted in the study: no control plot, US formulations instead of Canadian formulations, field fortifications not conducted with the intended end use products and climatic conditions not entirely representative of Canada.

The highest peak residue of 0.0124 µg/cm^2 detected at the California site after application of WG formulation was considered appropriate to use in the risk assessment for the WG formulation of thiamethoxam applied on turf. As non-quantifiable residues were detected at each test site after granular application, the LOQ value of 0.000359 µg/cm^2 was used in the risk assessment for the granular formulation of thiamethoxam applied on turf.

3.5.2.2 Postapplication Exposure and Risk Estimates

Potential exposure to thiamethoxam for workers entering treated turf to conduct turf maintenance activities (irrigating, scouting, aerating, fertilizing, mowing, hand weeding, rolling, harvesting and transplanting) was estimated using the generic agricultural transfer coefficients (TCs), coupled with the turf transferable residue values determined for the wettable granules or granular formulation from the TTR study.

Based on the NOAEL of 1.2 mg/kg bw/day, the calculated daily short-term exposures and MOEs were above the target MOE of 300 and do not present a health concern (Appendix I, Tables 3 and 4).

3.5.3 Residential Exposure and Risk Assessment

3.5.3.1 Handler Exposure and Risk

As only commercial uses are requested, a residential handler exposure and risk assessment was not required.

3.5.3.2 Postapplication Exposure and Risk

3.5.3.2.1 Determination of Hand Transfer Efficiency of Thiamethoxam Residues from Residential Turf following Granular and Liquid Applications

A hand press study was provided to estimate a toddler's hand-to-mouth non-dietary ingestion exposure. The dermal transfer rate was determined from the hand press study conducted with the help of ten adult human volunteers. Meridian™ 25WG was applied with a tractor drawn ground boom and Meridian™ 0.33G was applied with a tractor drawn Gandy Turf Tender drop Spreader at the label rate on one turf test plot each at one test site in North Carolina. Once sprays had dried, the transferable residues of thiamethoxam from the treated turf were sampled by each volunteer conducting seven consecutive wet hand presses on the treated turf, by exerting a downward pressure approximately 8 kg similar to that of a crawling child, for 6 seconds. The amount of residue that transferred to hands was collected by conducting two consecutive hand wipes using cotton gauze pads moistened with 0.01% aerosol OT (dioctyl sulfosuccinate) solution to simulate human saliva, and extracted residues were analyzed using applied Systems API 4000 LC/MS/MS. Average transferable residues to hand from the study were determined to be 0.114 µg/cm^2 (3.7% of the application rate) after Meridian™ 25WG application and less than limit of quantification of 0.0021 µg/cm^2 after Meridian™ 0.33G application.

However, the study was found to have major limitations: it was conducted with an experimental research tool; the application equipment was not relevant to the residential lawn applications; data were collected only from one test site and residue sampling intervals were not long enough to adequately characterize dissipation. Some minor limitations (similar to TTR study) were also noted. Based on the major limitations, the study was found to be unacceptable. Therefore, the data from the TTR study were used to estimate the dermal transfer rate to generate toddler's hand-to-mouth non-dietary (incidental) oral exposures.

3.5.3.2.2 Postapplication Residential Exposure and Risk Estimates

There is potential for an intermittent short-term dermal exposure to adults, youth and children who 1) may enter treated homeowner residential lawns for yard work activities (for example, mowing, watering), or as bystanders for recreational activities, 2) may enter treated commercial, other residential or recreational lawns including golf courses as bystanders to play golf or other activities. A separate short-term exposure and risk assessment was conducted for children (toddlers) to take into account their different physiological and behavioural parameters that can result in a different exposure (for example, hand-to-mouth non-dietary exposures through touching treated turf). For Veridian 0.33G, an additional accidental acute oral exposure and risk scenario for ingestion of granules was also considered.

The short-term residential exposure estimates are based on the assumptions as outlined in the United States Environmental Protection Agency (USEPA) draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments and the recommended revisions by the USEPA Science Advisory Council (USEPA 1997, 2001). The dermal exposures were generated using generic TC and thiamethoxam TTR values. Non-dietary oral exposures were assessed for toddlers potentially ingesting residues through hand-to-mouth transfer from the treated turf or other surfaces, by mouthing an object (grass) or by ingesting soil. In addition, oral ingestion of granules was considered for the granular formulation, although this is considered to be an acute, episodic exposure event rather than a repeated exposure. The total exposure for a child playing on treated turf was estimated as dermal exposure plus all non-dietary oral exposures (hand to mouth + object to mouth + ingestion of soil + ingestion of granules only for Veridian 0.33G). The estimated residential exposures and risks for Veridian 25WG and Veridian 0.33G are presented in Appendix I, Tables 5 and 6.

Calculated acute and short-term MOEs for adults and children exceeded the target MOE of 300. Thus, the potential exposures are below the levels that would be of a human health concern.

3.5.4 Bystander Exposure and Risk

See Residential Exposure and Risk Assessment (Section 3.5.3).

3.5.5 Aggregate Exposure and Risk

3.5.5.1 Aggregated Residential Exposure

As only commercial uses are requested, aggregation of residential exposures (residential handler plus residential postapplication) and risk was not required.

3.5.5.2 Aggregated Residential and Dietary Exposures

Aggregated postapplication residential risk resulting from exposure to thiamethoxam treated turf was estimated by aggregating total exposure from all sources and all routes of exposure, including food, drinking water and residential postapplication exposure for adults and children (for a toddler with a lowest body weight and highest potential for exposure). Acute and short-term exposure scenarios were considered.

3.5.5.2.1 Acute Aggregate Risk Assessment

An acute aggregate risk assessment for the highest single day exposure to thiamethoxam from acute dietary and acute residential exposure was not conducted, as it is improbable that an individual would be exposed to high-end dietary and residential exposures in the same day.

3.5.5.2.2 Short-term Aggregate Risk Assessment

Short-term aggregate exposure to thiamethoxam was estimated based on the contributions from food, drinking water and postapplication residential exposures (dermal and incidental oral components). Occupational (mixer/loader/applicator) exposures were not included in this aggregate assessment.

The chronic dietary (food and drinking water) exposure was considered representative of a typical exposure because it represents the average daily exposure over an individual's lifetime. Ingestion of granules is not aggregated in the short-term incidental oral scenario as this is considered to be episodic rather than a repeated exposure event.

The chronic dietary exposure values for a refined assessment were estimated based on Dietary Exposure Evaluation Model (DEEM), utilizing median values and experimental processing factors as available and prospective ground water (PGW) numbers for contribution from drinking water. The short-term dietary and residential aggregate exposure and risk were estimated by combining postapplication residential exposures from Appendix I, Tables 5 and 6 and estimated dietary exposures. Short-term aggregate estimates are presented in Appendix I, Tables 7 and 8 for Veridian 25WG and Veridian 0.33G, respectively. Target margins of exposure ($\geq$300) were achieved for the short-term aggregated exposures and risk, therefore, would not pose a concern to human health.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Thiamethoxam enters the environment when used as an insecticide on turf when applied as either a wettable granule or granule. Thiamethoxam is moderately persistent to persistent with the route of dissipation in the terrestrial environment being biotransformation in soil. For details on the fate and behaviour of thiamethoxam in the terrestrial environment, please refer to Evaluation Report ERC2007-01, *Thiamethoxam* and Regulatory Note REG2001-03, *Thiamethoxam, Helix, Helix XTra*. Field dissipation studies on bare ground soils showed that thiamethoxam was moderately persistent to persistent in soil, with DT_{50} values ranging from 48 to 239 days. However, no studies were submitted to demonstrate the dissipation on turf, which contains a high organic thatch layer. Therefore, a field dissipation study with thiamethoxam applied to turf is required.

The major transformation products are CGA 355190 (aerobic soil) and clothianidin (CGA 322704; terrestrial field dissipation). Clothianidin is a registered insecticide in its own right. Clothianidin is persistent in the environment with the main route of transformation in the terrestrial environment being in soil. Clothianidin is not expected to volatilize, however, it is expected to leach.

The ground water ubiquity score (GUS) was used to estimate the leaching potential of thiamethoxam and clothianidin. Based on the results, thiamethoxam and clothianidin are "leachers". The criteria of Cohen et al. (1984)[4] allow for an assessment of pesticide leachability based on laboratory data. Thiamethoxam and clothianidin met all but one criteria of a leaching compound. Based on these two methods of estimating leaching potential, thiamethoxam and clothianidin are expected to leach to groundwater. This was confirmed by a prospective ground water (PGW) study.

Thiamethoxam may enter the aquatic environment through spray drift or runoff and is slightly to moderately persistent. For details on the fate and behaviour of thiamethoxam in the aquatic environment, please refer to Evaluation Report ERC2007-01, *Thiamethoxam* and Regulatory Note REG2001-03, *Thiamethoxam, Helix, Helix XTra*. Additional information was also considered (Appendix I, Table 9).

Major transformation products in water were CGA 309335 (hydrolysis), CGA 353042 (water phototransformation), CGA 355190 (hydrolysis, aerobic aquatic, anaerobic aquatic), NOA 404617 (hydrolysis, aerobic aquatic and anaerobic aquatic), and NOA 407475 (anaerobic aquatic). The transformation product clothianidin is slightly persistent in the aquatic environment.

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[4] Cohen SZ, Creeger SM, Carsel RF, Enfield CG, 1984, Potential for pesticide contamination of groundwater resulting from agricultural uses, *IN* Drugger RF, Seiber JN (eds), Treatment and disposal of pesticide wastes, ACS Symposium Series No. 259, American Chemical Society, Washington, DC, pp.297–325.

Exposure concentrations for various environmental media, such as food, water and soil were estimated based on the use patterns of the thiamethoxam end-use products, Veridian 0.33G and Veridian 25WG.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (that is, protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

Risk of thiamethoxam and its related end-use products to terrestrial organisms was based upon the potential exposure from the proposed use pattern for each end-use product (Veridian 0.33G and Veridian 25WG), and the toxicity data as reported in Evaluation Report ERC2007-01, *Thiamethoxam*. Additional information on the toxicity of a wettable granule formulation of thiamethoxam to non-target terrestrial plants was also considered (Appendix I, Table 10).

Veridian 25WG

The screening level RQs for Veridian 25WG were assessed based on the maximum application rate (one application of 300 g a.i./ha) for earthworms, honeybees, birds, small mammals and terrestrial plants as these organisms may be exposed through direct contact during application, contact with treated plant material or from ingestion of contaminated food sources.

Honey bees are not expected to forage on turf, especially sod farms and golf courses, which are generally free of flowering plants. On occasion, flowering plants or weeds may be found in residential lawns, parks and recreational areas. Therefore, an on field assessment for bees is conducted. The screening level risk assessment for Veridian 25WG was conducted with the original laboratory bee acute oral LD_{50} and acute contact LC_{50} values of 5.6 g a.i./ha (0.005 µg a.i./bee) and 26.9 g a.i./ha (0.024 µg a.i./bee), respectively. The bee contact RQ is 11.2 and the bee oral RQ (based on oral exposure at the application rate) is 53.6 (Appendix I, Table 11). This indicates that there is potential risk to bees through both acute oral and acute contact exposure when flowering weeds are present on turf. An off field risk assessment was also conducted based on percent drift to off field flowering plants as flowering beds and plants may be planted or present adjacent to turf in golf course, residential lawns, parks and recreational areas. For drift, a refined EEC for a ground broadcast application of Veridian 25WG was calculated using a maximum percent drift deposition at one metre downwind of the site of application. A spray droplet size of 'medium' based on the American Society of Agricultural and Biological Engineers (ASAE) classification can be assumed for insecticide applied by field sprayer. For a 'medium' droplet size, the maximum spray drift deposition for ground boom sprayer to agricultural crops at one metre downwind from the point of application is 6% of the application rate.

The acute **contact** RQ in the modified scenario is 0.7 (based on drift to off field flowering plants), and thus the LOC is not exceeded (Appendix I, Table 12). The acute **oral** RQ is 3.2. To mitigate for potential risk, label statements are required. Additional studies, such as bee hive studies, are required to examine the chronic effects of thiamethoxam on bees and bee brood because of the systemic and persistent nature of thiamethoxam. The submitted bee hive study conducted in Germany was inadequate because of major deficiencies and deviations from guideline.

Veridian 25WG was found to have negligible risk to mammals and small- and medium-sized birds (Appendix I, Table 13). A reproductive risk was identified for large birds that graze (for example, Canadian geese), thus, a refined risk assessment was conducted.

In the screening risk assessment for birds and wild mammals, the conservative maximum residue estimates were used. The exposure scenario was modified to use mean residues values with the nomogram (Hoerger and Kenaga 1972, Kenaga 1973) modified according to Fletcher et al. (1994), and, as such, the LOC is not exceeded (RQ 0.43) (Appendix I, Table 15). Based on this modification and that Veridian 25WG is only applied once per year, the reproductive risk to large birds is considered to be minimal.

Data were submitted for terrestrial plants, which showed that no adverse effects were observed in plants treated up to 25 g a.i./ha, the highest treatment rate tested. Consequently, a NOEC of 25 g a.i./ha was assumed. The EEC is 300 g a.i./ha, which is equivalent to the maximum label rate for use on turf. The screening level RQ is therefore 12 (Appendix I, Table 11), which exceeds the LOC. Using a refined EEC based on a spray drift deposition of 6% at one metre downwind from the site of application, the risk quotient is 0.72 and does not exceed the level of concern (Appendix I, Table 16). Therefore, no risk to off-field terrestrial plants is expected when the subject product is applied at the proposed rate. A one-metre terrestrial buffer zone is specified on the Veridian 25WG product label to protect off-target plants from spray drift.

Veridian 0.33G

The risk to birds and small mammals from Veridian 0.33G was assessed based on the potential for exposure through ingestion of granules, as granules could be ingested incidentally, mistaken for a food source, or ingested as a source of grit by birds. Veridian 0.33G was found to have a negligible risk to small mammals and to birds. The RQ calculated with a conservative scenario and the risk based on reproductive endpoints for 1000 g birds was found to be 1.1 (Appendix I, Table 14), just exceeding the level of concern (LOC) of 1. Veridian 0.33G requires rainfall or irrigation to move the pesticide to the target pest (grubs) in the soil. Therefore, applicators are expected to irrigate turf after application, thus, limiting the number of granules that will be available. In addition, golf courses and turf farms are expected to have measures to control bird activity on their property to reduce turf damage, further limiting exposure. Based on this information, Veridian 0.33G is not expected to pose a reproductive risk to birds.

As discussed for Veridian 25WG, honey bees are not expected to forage on turf, especially sod farms and golf courses, which are generally free of flowering plants. On occasion, some flowering plants or weeds may be found in residential lawns, parks and recreational areas. In the case of the Veridian 0.33G granular formulation, thiamethoxam could be taken up through the roots of these plants or weeds and transported to leaves, flowers, nectar and pollen resulting in the potential for exposure through pollen and nectar. The potential for exposure of bees from granular application to turf is expected to be lower than exposure from application of currently registered products and foliar spray on turf. Although the risk to bees from granular turf application is expected to be low, cautionary label statements will be included.

No risk assessment for terrestrial plants was conducted for the use of Veridian 0.33G as no spray drift to off field plants is anticipated from granular application of thiamethoxam.

4.2.2 Risks to Aquatic Organisms

The risk of thiamethoxam and its related end-use products to freshwater aquatic organisms was based upon the toxicity data as reported in Evaluation Report ERC2007-01, *Thiamethoxam*. Additional information on the toxicity of four major aquatic transformation products CGA 355190, CGA 353042, NOA 404617 and NOA 407475 to chironomids was also considered (Appendix I, Table 10).

Aquatic organisms can be exposed to thiamethoxam as a result of drift and runoff from the application of Veridian 25WG and runoff from Veridian 0.33G. To assess the potential effects from exposure to thiamethoxam, the screening level EECs in the aquatic environment based on direct application to water were used as exposure estimates. The calculated EECs were those determined in water bodies of 15-cm depth for amphibians and 80-cm depth for all other aquatic organisms. For the screening level risk assessment for aquatic organisms the laboratory endpoints were adjusted using uncertainty factors to account for differences in species sensitivity and protection goals (for example; community, population and individual).

In those cases where the screening level assessments resulted in the LOC being exceeded, a refined assessment was conducted to further characterize the risk. Given the conservative assumptions in the screening level assessment which assumes a direct overspray to a water body, a refined assessment was conducted to further characterize the identified risk from drift and runoff to freshwater and marine organisms.

For drift of Veridian 25WG, a refined EEC for a ground broadcast application was calculated using a maximum percent drift deposition at one metre downwind of the site of application. A spray droplet size of 'medium' based on the American Society of Agricultural and Biological Engineers (ASAE) classification can be assumed for insecticide applied by field sprayer. For a 'medium' droplet size, the maximum spray drift deposition for ground boom sprayer to agricultural crops at one metre downwind from the point of application is 6% of the application rate (Wolf & Caldwell, 2001).

For runoff, a refined EEC using the maximum application rate for thiamethoxam in 1-ha water bodies of 15-cm depth (amphibians) or 80-cm depth (all other aquatic organisms) was estimated by PRZM-EXAMS. The EECs used for the RQ calculations were the most conservative estimates for a particular time interval representative of the exposure period of the toxicity test.

The respective acute toxicity EC_{50} values of CGA 355190, CGA 353042, NOA 404617 and NOA 407475 were 4.1, 56.4, 105 and 0.41 mg a.i./L. For details of all other endpoints, please refer to Evaluation Report ERC2007-01, *Thiamethoxam*. Calculated risk quotients for both freshwater and marine invertebrates demonstrate that the LOC for chronic effects was not exceeded (Appendix I, Table 17). The LOC was exceeded, however, for acute effects on chironomid (Appendix I, Table 17). A refined assessment for these effects was therefore conducted.

Given the conservative assumptions in the screening level assessment which assumes a direct overspray to a water body, a refined assessment was conducted to further characterize the risk from drift and runoff to chironomid (Appendix I, Table 18). Based on the revised RQs using the off-field EECs from drift and run-off concentrations estimated from PRZM-EXAMS modeling and the chronic invertebrate toxicity information, the level of concern for freshwater invertebrates was not exceeded. Therefore, no-spray buffer zones of one metre are required to protect sensitive habitats downwind of the site of application.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims

Seventeen field trials testing the effectiveness of thiamethoxam for control of larvae of European chafer, Japanese beetle, black turfgrass ataenius or masked chafer in turf were conducted from 1998 to 2007 in Canada and the United States. Different application rates of thiamethoxam, up to a maximum of 300 g a.i./ha, were evaluated and compared to industry standards. A single application was made for each trial. Each trial contained untreated control plots for comparison of pest population levels. Plots were assessed by taking a post-treatment sample of sod from each plot and counting the total number of live larvae. One postapplication assessment was made in each trial, one to three months after treatment.

Both formulations performed as well as the industry standards. No differences in efficacy between the two formulations were observed. Proposed label rates demonstrated control of all four pests. The higher rate was required for control of larger larvae. Therefore, it is recommended that applications be made earlier in the season, between peak adult flight and egg-hatch, so that early-instar larvae are exposed to the treatment. If applications are made later in the season, the higher rate of 300 g a.i./ha is recommended.

5.2 Phytotoxicity to Host Plants

No phytotoxicity was observed in any of the eight trials that rated phytotoxicity.

5.3 Economics

No market analysis was assessed for this product review.

5.4 Sustainability

5.4.1 Survey of Alternatives

Most of the products registered in Canada for control of these pests in turf contain either carbaryl, a carbamate insecticide, or the neonicotinoid insecticide imidacloprid. One product contains the organophosphate insecticide chlorpyrifos, and another contains pyrethrins and potassium salts of fatty acids. Thiamethoxam is a neonicotinoid insecticide and has a different mode of action from other registered products except for the products containing imidacloprid.

As a result of the re-evaluation of chlorpyrifos (Re-evaluation Note REV2007-01, *Update on the Re-evaluation of Chlorpyrifos*), use of chlorpyrifos on turf is limited to treatment of golf courses, industrial sites, highway medians and sod farms. In addition, as a result of the re-evaluation of carbaryl (Re-evaluation Note REV2003-06, *Update on Re-evaluation of Carbaryl in Canada*), the registrant has voluntarily discontinued broadcast application of liquid products containing carbaryl on residential lawns, including homes, schools, and any other areas where the general public including children may be exposed.

5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

Veridian 0.33G and Veridian 25WG are compatible with current turf management practices. Where treatment thresholds for larvae of European chafer, Japanese beetle, black turfgrass ataenius or masked chafer in turf exist, users are familiar with monitoring techniques to determine if and when applications are needed.

5.4.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Repeated use of insecticides with the same mode of action increases the probability of selecting resistant biotypes within an insect population. Therefore, Veridian 0.33G and Veridian 25WG should be used in rotation with insecticides that have different modes of action.

The Veridian 0.33G and Veridian 25WG labels include the resistance management statements, as per Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*.

5.4.4 Contribution to Risk Reduction and Sustainability

The contribution to risk reduction and sustainability was not assessed.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy (i.e. CEPA-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative).

Thiamethoxam and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Thiamethoxam does not meet all Track 1 criteria, and is not considered a Track 1 substance.
- Thiamethoxam does not form any transformation products that meet all Track 1 criteria.

Refer to Regulatory Note REG2001-03, *Thiamethoxam, Helix, Helix XTra* and Evaluation Report ERC2007-01, *Thiamethoxam* for full details on TSMP considerations for thiamethoxam. Additional TSMP considerations for the major transformation product clothianidin are summarized in Appendix I, Table 19.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade thiamethoxam and the end-use products Veridian 25WG and Veridian 0.33G do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.[9]

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5 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

8 DIR2006-02, *PMRA Formulants Policy.*

9 DIR2006-02, *PMRA Formulants Policy.*

7.0 Summary

7.1 Human Health and Safety

Mixer, loader, applicators handling Veridian 25WG or Veridian 0.33G and workers re-entering treated commercial, recreational or residential lawns are not expected to be exposed to levels of thiamethoxam that will result in an unacceptable risk when Veridian 25WG and Veridian 0.33G are used according to label directions. The personal protective equipment on the product label is adequate to protect workers.

Residential/bystander exposure to adults, youth and children contacting treated areas is not expected to result in unacceptable risk when Veridian 25WG or Veridian 0.33G are used according to label directions.

Aggregated dietary (food and water) and residential exposures for adults and children are also below the levels that may pose a human health concern.

7.2 Environmental Risk

Thiamethoxam is persistent and has the potential to be mobile in the environment. The major transformation product clothianidin is also persistent and has the potential to be mobile in the environment. Thiamethoxam and the major transformation product clothianidin can present a risk to bees when treated sites contain flowering plants.

7.3 Value

The data submitted to register Veridian 0.33G and Veridian 25WG are adequate to support the use of these products against larvae of the four labelled insect species in turf, when used according to the directions provided on the labels.

8.0 Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, has granted conditional registration for the sale and use of Thiamethoxam Technical, Veridian 0.33G and Veridian 25WG, containing the technical grade active ingredient thiamethoxam, to control European chafer, Japanese beetle, black turfgrass ataenius and masked chafer on turf.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been found acceptable when all risk-reduction measures are followed, as a condition of these registrations, additional scientific information is being requested from the applicant to confirm thiamethoxam's fate on turf and to ensure there are no long-term effects on bees. For more details, refer to the section 12 Notice associated with these conditional registrations. The applicant will be required to submit the following information by September 1, 2013.

Environment

- A field dissipation study with thiamethoxam applied to turf.
- A new hive study with thiamethoxam.

NOTE: The PMRA will publish a consultation document at the time when there is a proposed decision on applications to convert these conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

List of Abbreviations

µg	microgram(s)
a.i.	active ingredient
atm	atmosphere
bw	body weight
CAS	Chemical Abstracts Service
CEPA	Canadian Environmental Protection Act
cm	centimetre(s)
d	day(s)
DEEM	Dietary Exposure Evaluation Model
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the time required to observe a 90% decline in concentration)
dw	dry weight
EDE	estimated daily exposure
EEC	estimated exposure concentration
ER_{25}	effective rate for 25% of the population
ER_{50}	effective rate for 50% of the population
EXAMS	Exposure Analysis Modeling System
FC	food consumption
FIR	food ingestion rate
g	gram(s)
G	granular
ha	hectare(s)
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC	liquid chromatography
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOD	limit of detection
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
m^2	square metre(s)
m^3	cubic metre(s)
mg	milligram(s)
mL	millilitre(s)
MOE	margin of exposure
mol	mole
MS	mass spectrometry

N/A	not applicable
NAFTA	North American Free Trade Agreement
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OC	organic carbon content
OM	organic matter content
ORETF	Outdoor Residential Exposure Task Force
Pa	pascal(s)
PHED	Pesticide Handler Exposure Database
pK_a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	part(s) per billion
ppm	part(s) per million
PRZM	Pesticide Root Zone Model
RQ	risk quotient
$t_{1/2}$	half-life
TSMP	Toxic Substances Management Policy
TTR	turf transferable residue
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution
WG	wettable granules

Appendix I Tables and Figures

Table 1 Residue analysis

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Soil	AG-679 (System I)	CGA 293343	LC/MS/MS 292 to 210 m/z	5 ppb	1529722 1529723
		CGA 322704	LC/MS/MS 249 to 168 m/z		
		CGA 355190	LC/MS/MS 247 to 174 m/z		
		NOA 404617	LC/MS/MS 236 to 174 m/z		
	AG-679 (System II)	CGA 353042	LC/MS/MS 115 to 86 m/z	5 ppb	
		NOA 407474	LC/MS/MS 160 to 147 m/z		
Sediment	The methods submitted for soil were extended to sediment				
Water	REM 179-05 (Potable)	CGA 293343	HPLC-UV	0.05 ppb	1529724
		CGA 322704	HPLC-UV		
	REM 179-01 (Surface)	CGA 293343	HPLC-UV	0.5 ppb	1529724 1529725

Table 2 Mixer/loader/applicator exposure and risk for Veridian 25WG and Veridian 0.33G

Application equipment	Data source[a]	Formulation (application rate)	Area treated per day (ha)[b]	Dermal unit exposure (µg/kg ai)[a]	Dermal exposure (µg/kg bw/day)[c]	Inhalation unit exposure (µg/kg ai)[a]	Inhalation exposure (µg/kg bw/day)[c]	Daily exposures[e] (dermal + inhalation (mg/kg bw/d)	MOE[f] Target 300
Golf courses: Commercial Mixer/Loader/Applicator wearing long pants, a long-sleeved shirt and gloves									
Low pressure turf gun	ORETF	WG 0.3 kg a.i./ha	2	785	0.1682	4	0.0343	0.0002	6000
Groundboom	PHED		16	196.3	0.34	1.98	0.14	0.0005	2400
Backpack-spot	PHED		0.4	5609.6	0.24	63.1	0.11	0.00035	3400
Push-type spreader	ORETF	G 0.3 kg a.i./ha	2	474	0.1	16.5	0.1	0.00024	5000
Push-type spreader (spot)			0.4	474	0.02	16.5	0.0	0.00005	24000
Tractor drawn spreader	PHED		0	28.9	0.1	3.8	0.3	0.00039	3100

Application equipment	Data source[a]	Formulation (application rate)	Area treated per day (ha)[b]	Dermal unit exposure (µg/kg ai)[a]	Dermal exposure (µg/kg bw/day)[c]	Inhalation unit exposure (µg/kg ai)[a]	Inhalation exposure (µg/kg bw/day)[e]	Daily exposures[e] (dermal + inhalation (mg/kg bw/d)	MOE[f] Target 300
Sod farms: Commercial Mixer/Loader/Applicator wearing long pants, a long-sleeved shirt and gloves									
Low pressure turf gun	ORETF	WG 0.3 kg a.i./ha	2	785	0.1682	4	0.0343	0.00020	6000
Groundboom	PHED		30	196.3	0.6	1.98	0.3	0.00089	1300
Tractor drawn spreader	PHED	G 0.3 kg a.i./ha	30	28.9	0.1	3.8	0.5	0.00058	2100
Residential Lawns: Commercial Lawn Care Operator wearing long pants, a long-sleeved shirt and gloves									
Low pressure turf gun	ORETF	WG 0.3 kg a.i./ha	2	785	0.1682	4	0.0343	0.00020	6000
Backpack (spot)	PHED		0.4	5609.8	0.2	63.1	0.1	0.00035	3400
Push-type spreader	ORETF	G 0.3 kg a.i./ha	2	474	0.1	16.5	0.1	0.00024	5000
Push-type spreader (spot)			0.4	474	0.0	16.5	0.0	0.00005	24000

[a] Median unit exposures from Outdoor Residential Exposure Task Force (ORETF); best-fit unit exposures are used from Pesticide Handler Exposure Database (PHED)

[b] Area treated per day: PACR2007-02-Dicamba, USEPA policy 9, July 5, 2000).

[c] Dermal exposure (µg/kg bw/day) = (area treated per day × application rate of 0.3 kg a.i./ha for each formulation) × dermal unit exposure × 2.5% dermal absorption)/70 kg BW

[e] Inhalation exposure (µg/kg bw/day) = (area treated per day × application rate of 0.3 kg a.i./ha) × inhalation unit exposure/70 kg bw

[e] Daily exposures (mg/kg bw/day) = [dermal exposure (µg/kg bw/day) + inhalation exposure (µg/kg bw/day)] × 0.001 mg/µg

[f] MOE = NOAEL of 1.2 mg/kg bw/day from 2 generation reproductive study in rats for all routes ÷ daily exposures. Target MOE is 300

Table 3 Postapplication occupational exposure and risk for Veridian 25WG

Commercial turf	Activity	TC cm^2/h	TTR[a] µg a.i./cm^2	Duration (h)	Daily EXPO (mg/kg bw/d)[b]	Short-term MOE[c] Target 300
Sod farms	Harvesting treated turf	6800	0.0124	8	0.00024	5000
Sod farms and golf courses	Transplanting treated turf	6800	0.0124	8	0.00024	5000
Golf courses	Mowing, watering, cup changing, irrigation repair, miscellaneous grooming	3500	0.0124	8	0.000124	9700

Commercial turf	Activity	TC cm^2/h	TTR[a] µg a.i./cm^2	Duration (h)	Daily EXPO (mg/kg bw/d)[b]	Short-term MOE[c] Target 300
Sod farms	Mowing, watering, irrigation	3500	0.0124	8	0.000124	9700
Sod farms and golf courses	Aerating, fertilizing, hand pruning, mechanical weeding, scouting and seeding	500	0.0124	8	1.77E-05	67800

[a] day 0 highest peak residue from California test site from the TTR study

[b] Daily Exposure (mg/kg bw/day) = TC × TTR × duration × 2.5% dermal absorption)/(70 kg bw × 1000 µg/mg), where: TTR = Turf transferable residue on the day of application = 0.0124 µg/cm^2 for Veridian 25WG from the TTR study. TC = Transfer Coefficient, as outlined in the Interim revisions to USEPA policy 003.1 Golf Course and Sod Farm Transfer Coefficients, June 17th, 2003 and Internal PMRA memo of December 22, 2008. Duration = 8 hours/day for workers, and 4 hours/day for golfing activities. DA = dermal absorption of 2.5% for thiamethoxam (ERC 2007-01). BW = 70 kg adults

[c] NOAEL of 1.2 mg/kg bw/day. Target MOE is 300.

Table 4 Postapplication occupational exposure and risk for Veridian 0.33G

Commercial turf	Activity	TC (cm^2/h)	TTR (µga.i./cm^2)[a]	Duration (h)	Daily EXPO (mg/kg bw/day)[b]	Short-term MOE[c] Target 300
Sod farms	Harvesting treated turf	6800	0.000359	8	6.97E-06	172050
Sod farms and golf courses	Transplanting treated turf	6800	0.000359	8	6.97E-06	172050
Golf courses	Mowing, watering, cup changing, irrigation repair, miscellaneous grooming	3500	0.000359	8	3.59E-06	334260
Sod farms	Mowing, watering, irrigation	3500	0.000359	8	3.59E-06	334260
Sod farms and golf courses	Aerating, fertilizing, hand pruning, mechanical weeding, scouting and seeding	500	0.000359	8	5.13E-07	2339830

[a] day 0 highest peak residue value from California test site from the TTR study

[b] Daily Exposure (mg/kg bw/day) = TC × TTR × duration × 2.5% dermal absorption)/(70 kg bw × 1000 µg/mg). Where: TTR = Turf transferable residue on the day of application = 0.000359 µg/cm^2 for Veridian 0.33G from the TTR study. TC = (Transfer Coefficient), as outlined in the Interim revisions to USEPA policy 003.1 Golf Course and Sod Farm Transfer Coefficients, June 17th, 2003 and Internal PMRA memo of December 22, 2008. Duration = 8 hours/day for workers, and 4 hours/day for golfing activities. DA = dermal absorption of 2.5% for thiamethoxam (ERC 2007-01). BW = 70 kg adults

[c] NOAEL of 1.2 mg/kg bw/day. Target MOE is 300.

Table 5 Postapplication residential exposure and risk for Veridian 25WG

Residential scenario	Exposure (mg/kg bw/day)[a]				Total exposure[b]	Short-term MOE[c]
	Dermal	Non-dietary oral exposures				
		Hand-to-mouth	Turf mouthing	Ingestion of Soil		
Adult re-entering treated turf	0.000128	N/A	N/A	N/A	0.000128	9400
Adult golfer	0.000009	N/A	N/A	N/A	0.000009	133300
Youth golfer	0.000011	N/A	N/A	N/A	0.000011	109100
Toddler playing on turf	0.000215	0.00033	0.001	0.000013	0.001559	770

[a] Exposure (mg/kg bw/day) = dermal + non-dietary oral exposures if applicable (hand-to-mouth + turf mouthing + ingestion of soil). See equations below for each exposure.

[b] total exposures for adult and youth is the dermal exposure and total exposure for a toddler is the dermal + all oral exposures (hand to mouth + object mouthing + soil ingestion)

[c] NOAEL: 1.2 mg/kg bw/day; Target MOE: 300

Dermal Exposure (µg/kg bw/day) = (TTR × TC × DA × Duration)/BW, where:

- TTR = Turf transferable residue on the day of application = 0.0124 µg/cm^2 for Veridian 25WG,
- TC (cm^2/hr) = default Transfer Coefficients: 14500 for adults and 5200 for a toddler, 500 for adult golfer and 344 for youth golfers
- DA = Dermal absorption of 2.5% from ERC 2007-01. Duration = 2 hours of continuous contact with treated turf (95th percentile, USEPA SOPs - based on NHAPS and ORETF data) for homeowner on residential turf and 4 hrs for golfers on golf courses.
- BW = 70 kg adults (male/female); 39 kg for youths (10-12 year olds, male/female) and 15 kg for toddlers.

Hand-to-mouth oral exposure (mg/kg a.i./day) = TTR × surface area of hand × hand-to-mouth events for a child × saliva extraction factor × duration/15kg BW × 1000 µg/mg, where:

- TTR on the day of application = 0.0124 µg/cm^2 for Veridian 25WG from the TTR study
- Surface area of a toddler's hand = 20 cm^2 which represents the area of 2 to 3 fingers (USEPA 2001)
- Hand to mouth expressed in events/hr = assumed 20 events/hr with 100% reloading of the
- hands between each event (USEPA 2001)
- Saliva extraction factor, assumed 50%
- Duration = 2 hours of continuous contact with treated turf (95th percentile in USEPA SOPs and ORETF data)

Treated object (turf) to mouth ingestion exposure (mg/kg bw/day) = DFR × area of object (turf) mouthed × SEF /BW × 1000 µg/mg, where:

- Default DFR of 0.6 µg/cm^2 (20% of application rate) on the day of application for Veridian 25WG
- Area of object mouthed expressed in cm^2/day = 25 cm^2 of turf mouthed/day, the amount that can be grasped in one handful (upper-percentile from USEPA SOPs)
- SEF = 100% Saliva extraction factor
- BW = Child body weight = 15 kg for toddlers

Ingestion of Soil Exposure (mg/kg bw/day) = Application rate × IRS × F × CF/15 kg body weight of a toddler × 1000 µg/mg, where:

- AR = application rate of 3 µg/cm^2
- IRS = Soil ingestion rate expressed in g/day. 0.1 g of soil is consumed in a single event (upper percentile from USEPA 1996 SOPs). This is the total daily soil ingestion rate.
- F = Fraction of active ingredient available in uppermost 1 cm of soil, 100% per top 1 cm soil
- CF = Conversion factor to convert the volume units (cm^3) to weight units; 0.67 cm^3/g soil.

Table 6 Postapplication residential exposure and risk for Veridian 0.33G

Residential scenario	Exposure (mg/kg bw/day)[a]					Total exposure[b] (mg/kg bw/day)	Short-term MOE[c]	Acute MOE[d]
	Dermal	Oral						
		Hand-to-mouth	Turf mouthing	Ingestion of soil	Ingestion granules			
Adult re-entering treated turf	0.000004	N/A	N/A	N/A	N/A	0.000004	300000	N/A
Adult golfer	0.0000003	N/A	N/A	N/A	N/A	0.0000003	4000000	N/A
Youth golfer	0.0000005	N/A	N/A	N/A	N/A	0.0000005	2400000	N/A
Toddler playing on turf	0.000006	0.00001	0.001	0.00001	N/A	0.00103	1170	N/A
Toddler playing on turf and accidentally ingesting granules (acute exposure)	0.000006	0.00001	0.001	0.00001	0.066	0.067	N/A	520

[a] Exposure (mg/kg bw/day) = dermal + non-dietary oral exposures if applicable (hand-to-mouth + turf mouthing + ingestion of soil). See equations below for each exposure.

[b] Total exposures for adult and youth is dermal exposure and total exposure for a toddler is dermal + all oral exposures (hand to mouth + object (turf) mouthing + soil ingestion plus additional accidental ingestion of granules scenario

[c] NOAEL: 1.2 mg/kg bw/day; Target MOE: 300

[d] Acute NOAEL: 34.5 mg/kg bw/day: Target MOE: 300 for an acute exposure scenario of granular ingestion for a child playing on treated turf.

Dermal Exposure (µg/kg bw/day) = (TTR × TC × DA × Duration)/ BW, where:

- TTR = Turf transferable residue on the day of application = 0.000359 µg/cm^2 for Veridian 0.33G.
- TC (cm^2/hr) = default Transfer Coefficients: 14,500 for adults and 5,200 for a toddler, 500 for adult golfer and 344 for youth golfers.
- DA = Dermal absorption of 2.5% from ERC 2007-01
- Duration = 2 hours of continuous contact with treated turf (95th percentile, USEPA SOPs - based on NHAPS and ORETF data) for homeowner on residential turf and 4 hrs for golfers on golf courses.
- BW = 70 kg adults (male/female); 39 kg for youths (10-12 year olds, male/female) and 15 kg for toddlers.

Hand-to-mouth oral exposure (mg/kg a.i./day) = TTR × surface area of hand × hand-to-mouth events for a child × saliva extraction factor × duration/15kg BW × 1000 µg/mg, where:

- TTR on the day of application = 0.000359 µg/cm^2 for Veridian 0.33G from the TTR study
- Surface area of a toddler's hand = 20 cm^2 which represents the area of 2 to 3 fingers (USEPA 2001).
- Hand to mouth expressed in events/hr = assumed 20 events/hr with 100% reloading of the hands between each event (USEPA 2001)
- Saliva extraction factor, assumed 50%
- Duration = 2 hours of continuous contact with treated turf (95th percentile in USEPA SOPs and ORETF data)

Treated Object (Turf) to Mouth Ingestion Exposure (mg/kg bw/day) = DFR × area of object (turf) mouthed × SEF /BW × 1000 µg/mg, where:

- Default DFR of 0.6 µg/cm^2 (20% of application rate) on the day of application for Veridian 0.33G
- Area of object mouthed expressed in cm^2/day = 25 cm^2 of turf mouthed/day, the amount that can be grasped in one handful (upper-percentile from USEPA SOPs)
- SEF = 100% Saliva extraction factor
- BW = Child body weight = 15 kg for toddlers

Ingestion of Soil Exposure (mg/kg bw/day) = Application rate × IRS × F × CF/15 kg body weight of a toddler × 1000 µg/mg, where:

- AR = application rate of 3 µg/cm^2
- IRS = Soil ingestion rate expressed in g/day. 0.1 g of soil is consumed in a single event (upper percentile from USEPA 1996 SOPs). This is the total daily soil ingestion rate.
- F = Fraction of ai available in uppermost 1 cm of soil, 100% per top 1 cm soil
- CF = Conversion factor to convert the volume units (cm^3) to weight units; 0.67 cm^3/g soil.

Direct Ingestion of granules, acute exposure (mg/kg bw/day) for Veridian 0.33G only = Granular Ingestion rate (IR) of 0.3 g or 300 mg/day × 0.33% a.i /toddler body weight of 15kg.

Table 7 Short-term aggregate exposure and risk for Veridian 25WG

Subpopulation (age range/BW)	Postapplication residential exposure on turf (mg/kg bw/day)[a]	Chronic dietary (mg/kg bw/d)[b]	Aggregate exposure (mg/kg bw/day)[c]	Total MOE[d] Target 300
Adults (70 kg)	0.000128	0.000661	0.00079	1500
Toddler (1-2/15 kg)	0.00156	0.001844	0.00340	350
Adult golfer	0.000009	0.000661	0.00067	1800
Youth golfer	0.000016	0.000613	0.00063	1900

[a] Dermal and nondietary exposures aggregated.
[b] Based on chronic dietary exposures generated using DEEM.
[c] Aggregate exposure = postapplication residential + chronic dietary
[d] Total MOEs were calculated with a toxicology end point of 1.2 mg/kg bw/day from the combined reproductive toxicity studies for aggregation of all routes and all populations, divided by aggregate exposure.

Table 8 Short-term aggregate exposure and risk for Veridian 0.33G

Subpopulation (age range)	Postapplication residential exposure on turf (mg/kg bw/day)[a]	Chronic dietary (mg/kg bw/day)[b]	Aggregate exposure (mg/kg bw/day)[c]	Total MOE[d] Target 300
Adults (70 kg bw)	0.000004	0.000661	0.00067	1800
Toddler (15 kg bw)	0.00103	0.001844	0.00287	400
Adult golfer	0.0000003	0.000661	0.00066	1800
Youth golfer	0.0000005	0.000613	0.00061	2000

[a] Short-term dermal + short-term nondietary exposures aggregated, excluding accidental granular ingestion
[b] Based on chronic dietary exposures generated using DEEM.
[c] Aggregate exposure = postapplication residential + chronic dietary
[d] Total MOEs were calculated with a toxicology end point of 1.2 mg/kg bw/day from the combined reproductive toxicity studies for aggregation of all routes and all populations, divided by aggregate exposure. Short-term aggregate exposure and risk estimates for adults, youth and toddler were not of concern.

Table 9 Additional information on fate and behaviour in the environment

Property	Test substance	Value	Comments	Reference
Hydrolysis	Clothianidin (CGA322704)	pH 5–pH 9 = stable	Hydrolysis will not be an important route for transformation of clothianidin	1529731
Biotransformation in aerobic soil	Clothianidin (CGA322704)	DT_{50} = 379 days in soil	Clothianidin is classified as persistent in soils under aerobic conditions	1529746 1529747
Biotransformation in anaerobic soil	Clothianidin (CGA322704)	DT_{50} = 15.6 days	Clothianidin is classified as non-persistent in soils under anaerobic conditions	1529750

Table 10 Additional information on toxicity to non-target species

Organism	Exposure	Test substance	Endpoint value	Degree of Toxicity	Reference
Terrestrial vascular plants	Seedling emergence	Thiamethoxam 25WG	NOEC = 25 g a.i./ha (highest test rate)	N/A	1610615
	Vegetative vigour				
Chironomid	Acute	CGA 355190	LC_{50} = 4.1 mg/L	Moderately toxic	1529851
	Chronic	CGA 353042	NOEC = 56.4 mg/L	N/A	1529852
	Acute	NOA 404617	LC_{50} >105 mg/L	Practically non-toxic	1529853
	Chronic	NOA 407475	NOEC = 1.0 mg/L	N/A	1529854

Table 11 Risk of Veridian 25WG to terrestrial organisms (excluding birds and mammals)

Organism	Exposure	Endpoint value	EEC	RQ	LOC exceeded?
Earthworm	Acute	1000 mg a.i./kg	0.02 mg a.i./kg	0.0002	No
Bee	Oral	0.005 µg a.i./bee (5.6 g a.i./ha)	300 g a.i./ha	53.6	Yes
	Contact	0.024 µg a.i./bee (26.8 g a.i./ha)	300 g a.i./ha	11.2	Yes
Vascular plant	Seedling emergence	25 g a.i/ha	300 g a.i./ha	12	Yes
	Vegetative vigour				

Note: EEC – Estimated environmental concentration; RQ – Risk quotient; LOC – Level of Concern

Table 12 Refined risk of Veridian 25WG to bees at 300 g a.i./ha

Organism	Exposure	Endpoint value	EEC[a]	RQ	LOC exceeded?
Bee	Oral	0.005 µg a.i./bee (5.6 g a.i./ha)	18 g a.i./ha	3.2	Yes
	Contact	0.024 µg a.i./bee (26.8 g a.i./ha)	18 g a.i./ha	0.7	No

Note: EEC – Estimated environmental concentration; RQ – Risk quotient; LOC – Level of concern

[a] Based on drift of 6% to non-target plants (Wolf and Caldwell, 2001)

Table 13 Bird and mammal screening risk assessment for Veridian 25WG

Organism	Exposure	Endpoint value (mg/kg bw)	Feeding Guilds	Exposure		RQ[c] on field	LOC exceeded?
				EEC[a]	EDE[b]		
Birds							
20 g bird	Acute	57.6	Insectivore	59.28	15.12	0.26	No
			Granivore	10.15	2.59	0.04	No
			Frugivore	30.55	7.79	0.14	No
	Dietary	31	Insectivore	59.28	15.12	0.49	No
			Granivore	10.15	2.59	0.08	No
			Frugivore	30.55	7.79	0.25	No
	Reproduction	18	Insectivore	59.28	15.12	0.84	No
			Granivore	10.15	2.59	0.14	No
			Frugivore	30.55	7.79	0.43	No
100 g bird	Acute	57.6	Insectivore	59.28	11.8	0.20	No
			Granivore	10.15	2.02	0.04	No
			Frugivore	30.55	6.08	0.11	No
	Dietary	31	Insectivore	59.28	11.8	0.38	No
			Granivore	10.15	2.02	0.07	No
			Frugivore	30.55	6.08	0.20	No
	Reproduction	18	Insectivore	59.28	11.8	0.66	No
			Granivore	10.15	2.02	0.11	No
			Frugivore	30.55	6.08	0.34	No

Organism	Exposure	Endpoint value (mg/kg bw)	Feeding Guilds	Exposure		RQ[c] on field	LOC exceeded?
				EEC[a]	EDE[b]		
1000 g bird	Acute	57.6	Insectivore	10.15	0.59	0.01	No
			Granivore	10.15	0.59	0.01	No
			Frugivore	30.55	1.78	0.03	No
			Herbivore	369.6	21.47	0.37	No
	Dietary	31	Insectivore	10.15	0.59	0.02	No
			Granivore	10.15	0.59	0.02	No
			Frugivore	30.55	1.78	0.06	No
			Herbivore	369.6	21.47	0.70	No
	Reproduction	18	Insectivore	10.15	0.59	0.03	No
			Granivore	10.15	0.59	0.03	No
			Frugivore	30.55	1.78	0.10	No
			Herbivore	369.6	21.47	1.20	Yes
Mammals							
15 g mammal	Acute	87.1	Insectivore	59.28	8.69	0.10	No
			Granivore	10.15	1.49	0.02	No
			Frugivore	30.55	4.48	0.05	No
	Reproduction	202	Insectivore	59.28	8.69	0.04	No
			Granivore	10.15	1.49	0.01	No
			Frugivore	30.55	4.48	0.02	No
35 g mammal	Acute	87.1	Insectivore	10.15	7.62	0.09	No
			Granivore	10.15	1.3	0.01	No
			Frugivore	30.55	3.93	0.05	No
			Herbivore	369.6	47.52	0.54	No
	Reproduction	202	Insectivore	10.15	7.62	0.04	No
			Granivore	10.15	1.3	0.01	No
			Frugivore	30.55	3.93	0.02	No
			Herbivore	369.6	47.52	0.23	No

Organism	Exposure	Endpoint value (mg/kg bw)	Feeding Guilds	Exposure		RQ[c] on field	LOC exceeded?
				EEC[a]	EDE[b]		
1000 g mammal	Acute	87.1	Insectivore	10.15	0.7	0.01	No
			Granivore	10.15	0.7	0.01	No
			Frugivore	30.55	2.1	0.02	No
			Herbivore	369.6	25.39	0.29	No
	Reproduction	202	Insectivore	10.15	0.7	0.003	No
			Granivore	10.15	0.7	0.003	No
			Frugivore	30.55	2.1	0.01	No
			Herbivore	369.6	25.39	0.13	No

Note: RQ – Risk quotient; LOC – Level of concern

[a] EEC = Estimated environmental concentration: For birds and mammals, the EEC takes into account the maximum seasonal cumulative rate on vegetation and is calculated using PMRA standard methods based on the Hoerger and Kenaga nomogram as modified by Fletcher (1994)

[b] EDE = Estimated dietary exposure; calculated for each bird or mammal size based on the EEC on appropriate food item for each food guild (at the screening level, the most conservative EEC for each food guild was used). The EDE was calculated using the following formula: (FIR/BW) × EEC. For each body weight (BW), the food ingestion rate (FIR) was based on equations from Nagy (1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used; for mammals, the "all mammals" equation was used:
Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = $0.398(\text{BW in g})^{0.850}$
All Birds Equation (body weight > 200 g): FIR (g dry weight/day) = $0.648(\text{BW in g})^{0.651}$
All Mammals Equation: FIR (g dry weight/day) = $0.235(\text{BW in g})^{0.822}$

[c] RQ = expsoure/toxicity; RQs < 0.1 were not calculated to show all decimal points;

Table 14 Bird screening risk assessment for Veridian 0.33G

Species	Toxicity Test		Endpoint in # seeds	Estimated Daily Exposure in # granules	RQ
20 g small bird	Single Dose Oral	$LD_{50}/10$	13963.6	2253.0	0.2
	Dietary	$LD_{50}/10$	7504.8	2253.0	0.3
	Reproduction	NOEL	4329.7	2253.0	0.5
100 g medium bird	Single Dose Oral	$LD_{50}/10$	69818.2	2620.0	0.0
	Dietary	$LD_{50}/10$	37523.9	2620.0	0.1
	Reproduction	NOEL	21648.4	2620.0	0.1
1000 g large bird	Single Dose Oral	$LD_{50}/10$	698181.8	240021.0	0.3
	Dietary	$LD_{50}/10$	375238.8	240021.0	0.6
	Reproduction	NOEL	216483.9	240021.0	1.1[a]

[a] As Veridian 0.33G requires irrigation or rainfall to be effective the granules are not expected to be available for consumption for a long enough period for the birds to consume the very large number of granules required to reach this endpoint.

Table 15 Refined reproduction risk of Veridian 25WG to large birds at 300 g a.i./ha using mean estimated foliar concentrations

Organism	Exposure	Endpoint value (mg/kg bw)	Feeding Guilds	Exposure		RQ on field	LOC exceeded?
				EEC	EDE		
1000 g bird	Reproduction	18	Insectivore	33.1	1.9	0.1	No
			Granivore	7.1	0.4	0.02	No
			Frugivore	14.1	0.8	0.05	No
			Herbivore	132.0	7.7	0.4	No

Table 16 Refined risk of Veridian 25WG to terrestrial plants

Organism	Exposure	Endpoint value	EEC[a]	RQ	LOC exceeded?
Terrestrial plants	Seedling emergence	25 g a.i./ha	18 g a.i./ha	0.72	No
	Vegetative vigour				

[a] Based on 6% spray drift deposition for medium field boom sprayer application

Table 17 Risk to aquatic organisms

Organism	Compound	Exposure	Endpoint value (mg a.i./L)	EEC (mg a.i./L)	RQ	LOC exceeded?
Freshwater species						
Daphnia magna	Thiamethoxam	Acute	½ LC_{50} = 52.9	0.038	0.0007	No
		Chronic	NOEC = 100.5	0.038	0.0004	No
Chironomid	Thiamethoxam	Acute	½ LC_{50} = 0.0175	0.038	**2.2**	**Yes**
		Chronic	NOEC = 0.005	0.038	**7.6**	**Yes**
	CGA 355190	Acute	½ LC_{50} = 2.05	0.038	0.02	No
		Chronic	NOEC = 2.6	0.038	0.01	No
	CGA 353042	Chronic	NOEC = 56.4	0.038	0.0007	No
	NOA 404617	Acute	½ LC_{50} = 52.5	0.038	0.0007	No
		Chronic	NOEC = 53	0.038	0.0007	No
	NOA 407475	Chronic	NOEC = 0.41	0.038	0.1	No
Rainbow trout	Thiamethoxam	Acute	1/10 LC_{50} = 10	0.038	0.004	No
		ELS	NOEC = 20	0.038	0.002	No
Bluegill sunfish	Thiamethoxam	Acute	1/10 LC_{50} = 11.4	0.038	0.003	No
Amphibian	Thiamethoxam	Acute	1/10 LC_{50} = 10	0.2	0.02	No
Freshwater alga	Thiamethoxam	Acute	½ EC_{50} = 50	0.038	0.0008	No
Vascular plant	Thiamethoxam	Dissolved	½ EC_{50} = 45.1	0.038	0.0008	No
Marine species						
Crustacean	Thiamethoxam	Acute	½ LC_{50} = 3.4	0.038	0.01	No
		Chronic	NOEC = 2	0.038	0.02	No
Mollusk	Thiamethoxam	Acute	½ LC_{50} = 59.5	0.038	0.0006	No
Salmonid	Thiamethoxam	Acute	1/10 LC_{50} = 11.1	0.038	0.003	No
Marine alga	Thiamethoxam	Acute	Not data provided			Unknown

Note: EEC – Estimated environmental concentration; RQ – Risk quotient; LOC – Level of concern

Table 18 Refined risk assessment for chironomid

Organism	Compound	Exposure	Endpoint value (mg a.i./L)	EEC (mg a.i./L)	RQ	LOC exceeded?
Percent drift deposition						
Chironomid	Thiamethoxam	Acute	½ LC_{50} = 0.0175	0.0023	0.13	No
		Chronic	NOEC = 0.005	0.0023	0.46	No
Ecoscenario						
Chironomid	Thiamethoxam	Acute	½ LC_{50} = 0.0175	0.0023	0.13	No
		Chronic	NOEC = 0.005	0.0017	0.34	No

Note: EEC – Estimated environmental concentration; RQ – Risk quotient; LOC – Level of concern

Table 19 Additional Toxic Substance Management Policy considerations

TSMP Track 1 criterion	TSMP Track 1 criterion value		Transformation product clothianidin endpoint
CEPA[a] toxic or CEPA toxic equivalent[b]	Yes		Yes
Predominantly anthropogenic[c]	Yes		Yes
Persistence[d]	Soil	Half-life ≥ 182 days	Half-life 495–990 days
	Water	Half-life ≥ 182 days	Half-life unknown
	Sediment	Half-life ≥ 365 days	Half-life unknown
	Air	Half-life ≥ 2 days or evidence of long range transport	Half-life or volatilisation is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (1.3×10^{-10} Pa) and Henry's law constant (9.8×10^{-16} atm m^3/mol)
Bioaccumulation[e]	Log $K_{ow} \geq 5$		0.7
	BCF ≥5000		Value or not available
	BAF ≥5000		Value or not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.

[a] CEPA – Canadian Environmental Protection Act

[b] All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e. all other TSMP criteria are met).

[c] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[d] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

[e] Field data (e.g. BAFs – bioaccumulation factor) are preferred over laboratory data (e.g. BCFs – bioconcentration factor) which, in turn, are preferred over chemical properties (e.g. log K_{ow}).

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